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(54) Medical device for implantation into living bodies

(57) The medical device (1) for implantation into living bodies has first (2a) and second (2b) types of surface areas with different roughness. The first type of surface area consists of a plurality of isle-like surface portions (2a) of lower roughness surrounded by the second type of surface area (2b) consisting of a continuously interconnected surface portion of higher roughness.

The device allows for an improved adhesion of the soft tissues (3) to the implant which can be controlled by changing the ratio of the two types of surface areas.

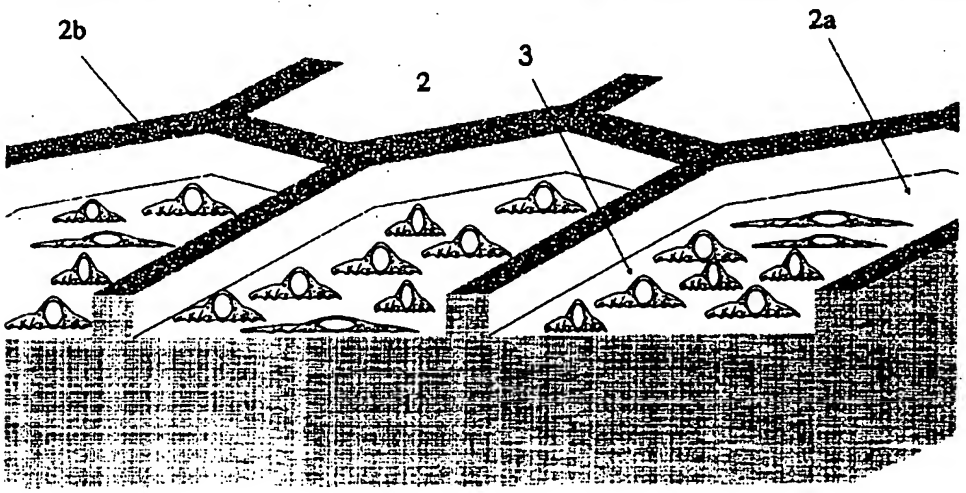

Fig 3

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Description

This invention relates to a medical device for implantation into living bodies according to the preamble of claim 1.

Postoperative infections still play an important role in jeopardising the result of surgical treatment of bone fractures and joint disease. The relative incidence of infections is 1 - 2 % at least.

It is evident that resistance to infection (provided good implant materials are used) at the implant/soft tissue interface is determined by the strength of adhesion of the connective tissue to the implant. The extremities of the situation are:

1. Interface motion causing the formation of a fibrous capsule, surrounding the implant with a continuous liquid phase favouring the spread of bacterial infection and impeding the mobile cellular defense of the body.
2. Strong adhesion of the soft tissue to the implant allows minimal fibrous tissue formation, thus confining a bacterial contamination. Close contact of blood vessels to the implant improves the body's defense. The draw back of strong adhesion of the soft tissue to the implant is that it can cause tissue trauma during removal of the implant after fracture healing.

The invention as claimed is intended to cure these problems of too much or too little adhesion of the soft tissues to the implant. Varying the degree of rough/smooth surface area will allow the problems to be solved in different parts of the body.

The invention will have numerous applications in the body for all implant plates and most prosthesis. Variations of the invention include the following:

1. A network of fine rough surface with smooth compartments in between covering at least partially the surface of the prosthesis or implant.
2. A raised network of fine rough surface with smooth compartments below in between the network covering at least partially the surface of the prosthesis or implant.

The rough surface may be made by etching with an acid or mixture of acids as for example with standard cleaning of an implant plate. If a raised rough surface was to be used in combination with a lower smooth surface the pattern could be stamped onto the implant and the lower surface protected before making the raised pattern rough with etching. The rough / smooth surface could also be made by photoetching of a thin foil to produce the network followed by acid etching of the network produced. The foil would then be bonded onto the smooth surface of the implant, giving a raised rough surface.

The design contains numerous additional advantages to those stated in the initial problem for minimising possibility of bacterial infection.

In the example of the raised network, the fine rough surface protects the initial invading cells, such as fibroblastics cells, from shear forces from body fluid motion during the important initial stages of cell attachment and proliferation. The smooth surface promotes cell spreading and early attachment of the cells therefore accelerating the cell cycle with the consequence of increasing proliferation of cells. The raised network also separates compartments of smooth surface which prevents bacteria from spreading from one compartment to the next. When the soft tissue comes to rest on the implant the rough surface will enable optimal adhesion of the tissue to the implant via the tissue's extracellular matrix and in the case of raised rough surface the compartments which will have been filled by invading cells will act as plugs of tissue which will attach to the overlying soft tissue and prevent motion of the soft tissue over the implant or prosthesis, preventing tissue trauma.

Examples of the use of the rough and smooth surface would include plates with this combination surface on the uppersurface of the plate where it is in contact with the soft tissue. The rough and smooth surface would be beneficial to all metallic plates and also to biodegradable ones. In the case of any biodegradable plates and other implants or prosthesis' the amount of rough surface compared to the amount of smooth surface could be increased since the implant or prosthesis should degrade into the body and would not need to be taken out. Therefore the amount of adhesion could be allowed to be much greater than for an implant or prosthesis that would have to be taken out. A pacemaker prosthesis could have the combination rough and smooth surface on all of it's area in contact with living tissue to promote good adhesion and minimise the chance of infection.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming part of this disclosure. For the better understanding of the invention, its operating advantages and specific objects attained by its use, reference should be had to the accompanying drawings, examples and descriptive matter in which are illustrated and described preferred embodiments of the invention.

In the drawings:

Fig. 1 is a cross section of a conventional implant or prosthesis having either a rough or smooth surface, but not a combination of both;

Fig. 2 is a cross section of an implant of prosthesis with the invention of a combination of rough and smooth areas both on the same surface of the implant or prosthesis;

Fig. 3 is a cross section of an implant or prosthesis with the invention of a combination of a raised rough surface separating compartments of smooth surface in between; and

Fig. 4 is an example of the rough and smooth surface combined as applied to an implant plate from an uppersurface view.

Figure 1 shows a prior art bone plate 1 having an uppersurface 2 of uniform roughness. Roughness can be either very low as with polished plates or can be significant as in the case of sandblasted or etched bone plates. The cell, e.g. fibroblasts 3 will adhere to the uppersurface 2 of the bone plate 1 according to its roughness.

In Fig. 2 the uppersurface 2 of the bone plate 1 according to the invention is divided into first and second types of surface areas with different roughness. The first type of surface area consists of a plurality of isle-like surface portions 2a of lower roughness surrounded by the second type of surface area consisting of a continuously interconnected surface portion 2b of higher roughness, in the form of a network, for example of hexagonal structure. The total surface area of lower roughness is equal to $A_1 = \Sigma a_j$, where a_j is the surface area of the individual isle-like surface portions. The total surface of the network of higher roughness is equal to A_2. The control of the tissue adhesion is possible by changing the ratio of A_1/A_2 which typically is in the region of 1 - 10, preferably 2 - 5.
The smooth surface portions 2a promote spreading and early attachment of the fibroblasts 3.
The function of the rougher surfaces 2b of the network is to provide for stronger attachment of the extracellular matrix (collagen).

Fig. 3 shows a preferred embodiment of the invention in which the uppersurface 2 of the bone plate 1 is divided in the same manner as in the example of Fig. 2 but where the rough surface portion 2b is raised with respect to the surface portions 2a of lower roughness, thereby separating the latter to form compartments of smooth surface in between the rough surface portion 2b. The surface portion 2b of higher roughness protects the fibroblastic cells 3 initially invading the lower smooth compartments of surface portions 2a.
The preferred method of producing such a surface is firstly acid etching of the complete surface, e.g. with hydrofluoric acid in the case of titanium which will lead to about 1 µ RMS (i.e. root mean square) roughness and secondly stamping the etched surface with a patterned tool. The stamping of the lowered regions will lead to a significant decrease in roughness, e.g. stamping to a depth of about 100 µ reduced the RMS value of the roughness to about 0.4 µ.

Fig. 4 shows the total upperside 2 of a bone plate 1 with holes 4 having the inventive combination of portions of lower roughness 2a surrounded by a surface portion of higher roughness 2b as shown in detail in Fig. 3.

While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be obvious for those skilled in the art that various changes and modifications may be made therein without departing from the true spirit and scope of the present invention.

Claims

1. Medical device for implantation into living bodies having first and second types of surface areas with different roughness, wherein the first type of surface area consists of a plurality of isle-like surface portions of lower roughness surrounded by the second type of surface area consisting of a continuously interconnected surface portion of higher roughness.

2. Medical device according to claim 1, wherein the ratio A_1/A_2 between the total surface area of the first type $A_1 = \Sigma a_j$, a_j being the surface area of the isle-like surface portions, to the total surface area of the second type A_2 is in the range between 1 - 10, preferably 2 - 5.

3. Medical device according to claim 1 or 2, wherein the RMS (root mean square) roughness of the said first type of surface area is less than 1.0 µ, preferably less than 0.5 µ.

4. Medical device according to claim 1 or 2, wherein the RMS (root mean square) roughness of the said second type of surface area is larger than 0.5 µ, preferably larger than 1.0 µ.

5. Medical device according to one of the claims 1 - 4, wherein the roughness of the said second type of surface area is at least two times higher than the roughness of the said first type of surface area.

6. Medical device according to one of the claims 1 - 5, wherein said plurality of discontinuous surface portions of the first type of surface area are in the form of regular polygons, preferably squares or hexagons.

7. Medical device according to one of the claims 1 - 6, wherein first type of surface area is located at a lower level than second type of surface area, said plurality of discontinuous surface portions of lower roughness forming depressions in said continuous surface portion of higher roughness.

8. Medical device according to one of the claims 1 - 7, wherein the distance between the levels of said first and second types of surface areas is in the range of 5 - 200 µm, preferably 30 - 80 µm.

9. Medical device according to one of the claims 1 - 8, wherein the surface a_j of one of said discontinuous surface portions of said first type of surface area is larger than 0.1 mm².

10. Medical device according to one of the claims 1 - 8, wherein the surface a_i of one of said discontinuous surface portions of said first type of surface area is smaller than 10 mm^2.

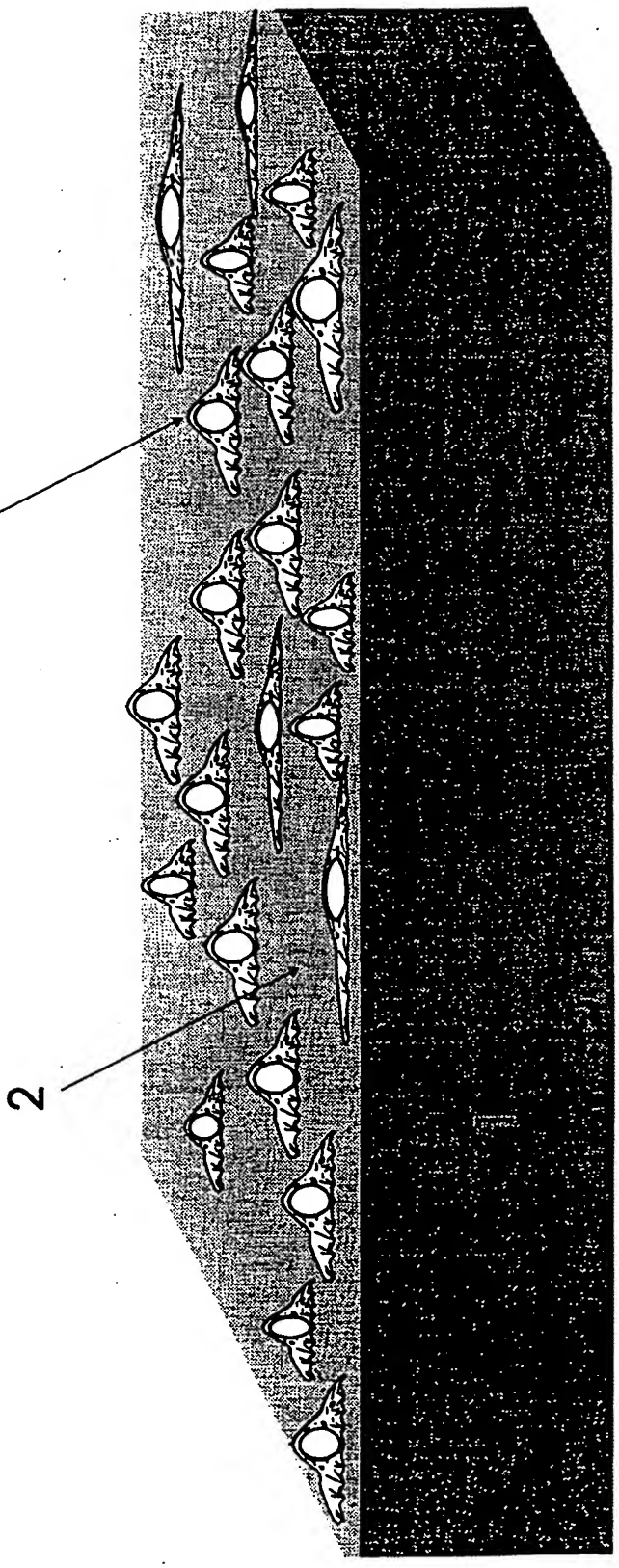

Fig.1

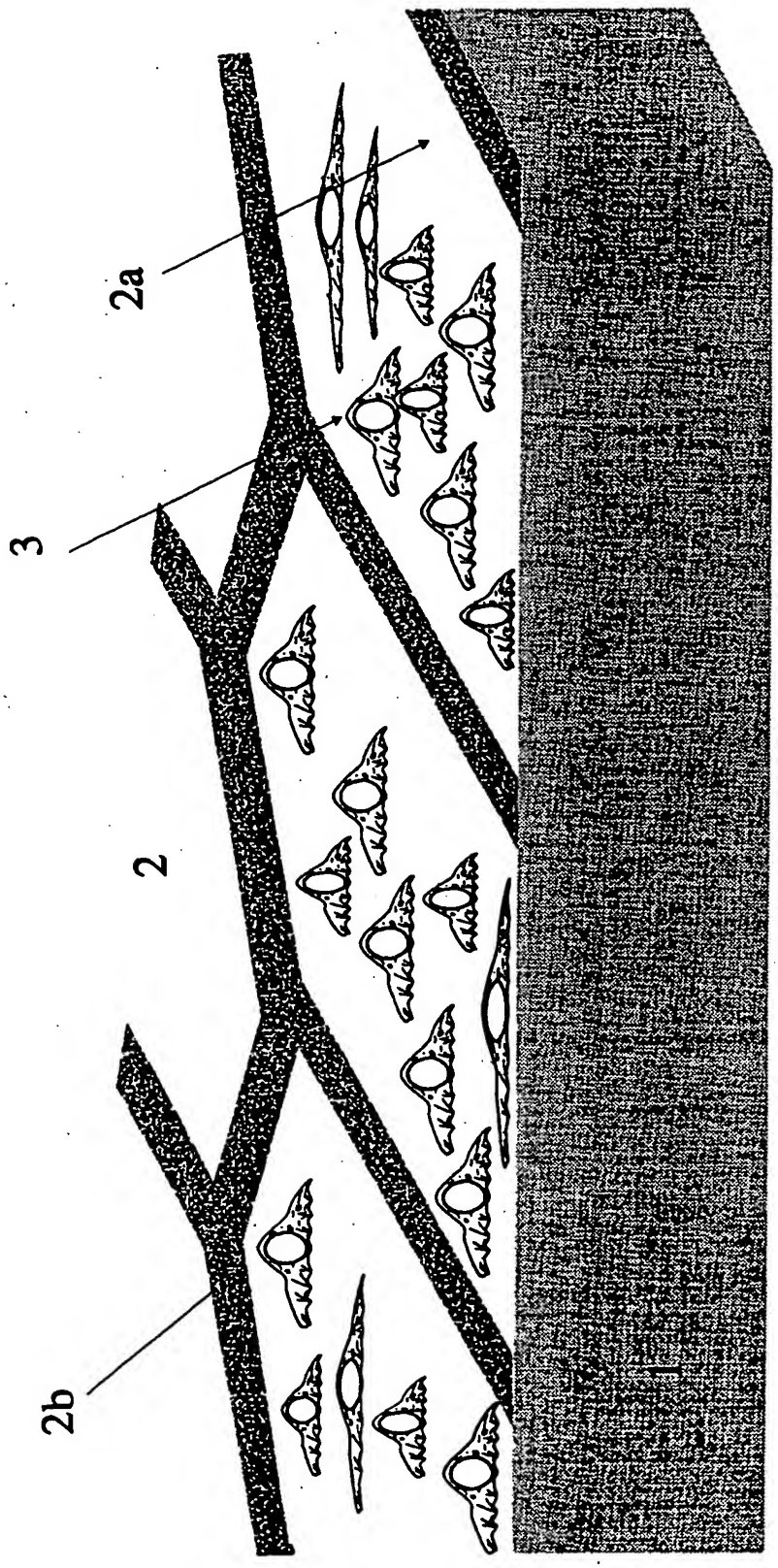

Fig.2

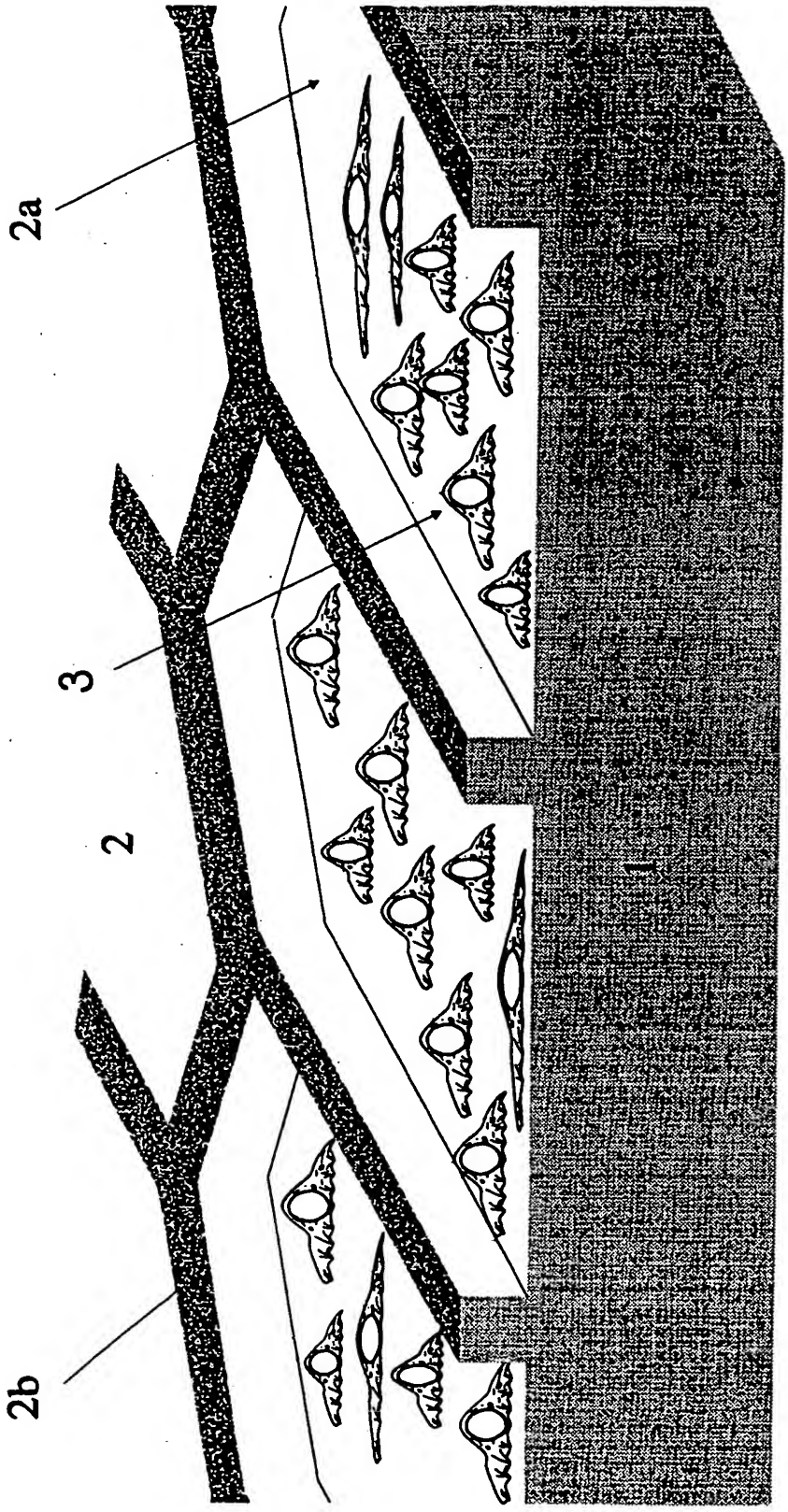

Fig 3

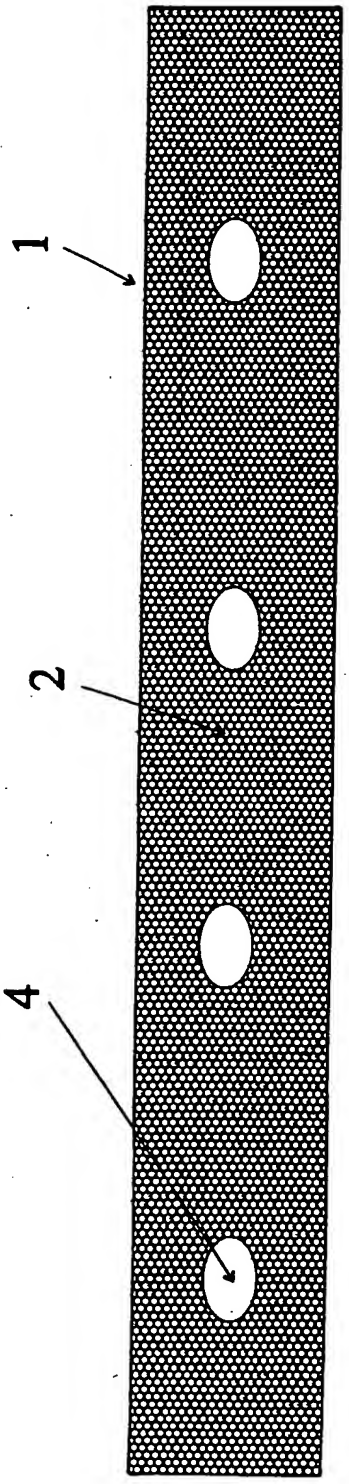

Fig.4

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EUROPEAN SEARCH REPORT

Application Number
EP 95 10 0829

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US-A-4 767 418 (W.D. DEININGER ET AL.) * column 2, line 64 - column 3, line 2; figure 4 * * column 4, line 1 - line 24; figure 9 *	1-8,10	A61F2/30 A61B17/58
X	US-A-4 865 603 (D.G. NOILES) * abstract; figures 8,15 * * column 6, line 21 - line 39 *	1,2,5-8,10	
X	DE-A-31 16 040 (FRAUNHOFER) * page 4, line 14 - page 5, line 22; claim 1; figures 1,2 *	1,9,10	
A	EP-A-0 359 575 (CLEMSON UNIVERSITY) * abstract; figure 13 *	2,6-8,10	
A	WO-A-93 00870 (THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA) * abstract *	1,2,5-7	
A	EP-A-0 388 576 (INSTITUT STRAUMANN) * abstract; figure 3; table *	3,4	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61F A61B
P,X A	EP-A-0 610 837 (ACROMED) * column 4, line 43 - line 58; figures 5,7 * *	1,2 3,4	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	4 April 1995	Wolf, C

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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